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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,558	03/14/2001	Michael M. Becker	GP068-05.CN3	3920

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EXAMINER	
CALAMITA, HEATHER	
ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/808,558	BECKER ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *480-518* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *480-518* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 16, 2006, has been entered.

Status of Application, Amendments, and/or Claims

2. Claims 480-518 are pending and under examination. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 480-518 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carmo-Fonseca et al. (EMBO, 1991) as evidenced by Iribarren et al. (PNAS 1990) in view of Tsang (USPN 5,837,442)

With regard to claims 480 and 499, Carmo-Fonseca et al. teach a probe molecule comprising first and second base regions capable of hybridizing to each other under nucleic acid assay conditions to form a hybrid containing at least one ribonucleotide modified to include a 2'-O-alkyl substitution to the

ribofuranosyl moiety, wherein the probe forms a stable double-stranded complex with the nucleic acid sequence but not with a non-targeted nucleic acid under nucleic acid conditions such that the target nucleic acid sequence can be detected, wherein the complex comprises a single stranded form of the probe (see p. 1863 col. 2 final paragraph lines 4-8 and p. 1872 col. 2 table 1, where the probes comprise a 2'-O-methyl substitution and form a stable double stranded complex with the target snRNA).

With regard to claims 481 and 501, Carmo-Fonseca et al. teach the first base region contains at least one ribonucleotide modified to include a 2'-O-alkyl substitution to the ribofuranosyl moiety and the first base region complexes with the target nucleic acid sequence under nucleic acid assay conditions (see p. 1863 col. 2 final paragraph lines 4-8 and p. 1872 col. 2 table 1, where the probes comprise a 2'-O-methyl substitution and form a stable double stranded complex with the target snRNA).

With regard to claims 482 and 502, Carmo-Fonseca et al. teach the portion of the first base region includes a cluster of at least about 4 ribonucleotides modified to include a 2'-O-alkyl substitution to the ribofuranosyl moiety (see p. 1863 col. 2 final paragraph lines 4-8 and p. 1872 col. 2 table 1, where the probes comprise a 2'-O-methyl substitution and form a stable double stranded complex with the target snRNA).

With regard to claims 483, 485, 487, 503, 505 and 507, Carmo-Fonseca et al. teach the first base region complexes with the target nucleic acid sequence under the nucleic acid assay condition (see p. 1863 col. 2 final paragraph lines 4-8 and p. 1872 col. 2 table 1, where the probes comprise a 2'-O-methyl substitution and form a stable double stranded complex with the target snRNA).

With regard to claims 484 and 504, Carmo-Fonseca et al. the portion of the first base region capable of froming a hybrid with the second base region under nucleic acid assay conditions includes at least one nucleotide which is not a ribonucleotide modified to include a 2'-O-alkyl substitution to the ribofuranosyl moiety (see p. 1863 col. 2 final paragraph lines 4-8 and p. 1872 col. 2 table 1, where the

probes comprise a 2'-O-methyl substitution and form a stable double stranded complex with the target snRNA).

With regard to claims 486 and 506, Carmo-Fonseca et al. teach each nucleotide of the portion of the first base region capable of forming a hybrid with the second base region under nucleic acid assay conditions is a ribonucleotide modified to include a 2'-O-alkyl substitution to the ribofuranosyl moiety (see p. 1863 col. 2 final paragraph lines 4-8 and p. 1872 col. 2 table 1, where the probes comprise a 2'-O-methyl substitution and form a stable double stranded complex with the target snRNA).

With regard to claims 488 and 508, Carmo-Fonseca et al. teach each nucleotide of the probe is a ribonucleotide modified to include a 2'-O-alkyl substitution to the ribofuranosyl moiety (p. 1872 col. 2 table 1).

With regard to claims 489 and 509, Carmo-Fonseca et al. teach the hybrid formed between the first and second base regions is more stable than a hybrid formed between unmodified forms of the first and second base regions (see p. 1863 col. 2 final paragraph lines 4-8, where it is disclosed the probes hybridize stably and are resistant to nuclease degradation due to the modification).

With regard to claims 490, 491 510 and 511, Carmo-Fonseca et al. teach the probe includes a conjugate molecule joined to the probe at a site located within the cluster of the first base region (see p. 1872 col. 2 table 1, where the conjugate molecule is the label).

With regard to claims 492 and 512, Carmo-Fonseca et al teach the first and second base regions are contained within an oligonucleotide that is between 10 and 100 bases in length (see p. 15 line 30).

With regard to claims 493, 494, 513 and 514, Carmo-Fonseca et al. teach the label comprises a fluorescent molecule (see p. 1872 col. 2 table 1).

With regard to claims 495, 496, 515 and 516, Carmo-Fonseca et al. teach the target nucleic acid comprises RNA and ribosomal RNA (see p. 1863 col. 2 final paragraph lines 4-8).

With regard to claims 497 and 517, Agrawal et al. teach a target sequence contained within the target nucleic acid includes a double stranded region (see p. 1863 col. 2 final paragraph lines 4-8, where snRNAs have hairpins which are double stranded regions).

With regard to claims 498 and 518, Carmo-Fonseca et al. teach the 2'-O-alkyl substitution to the ribofuranosyl moiety is a 2'-O-methyl substitution (see p. 1863 col. 2 final paragraph lines 4-8, where the probes of Iribarren are referenced and Iribarren substituted with 2'-O-methyl).

Carmo-Fonseca et al. do not teach all of the limitations of claims 480-518, specifically Carmo-Fonseca et al. do not teach kit or a reaction mixture further comprising a nucleic acid polymerase, nucleotide triphosphates and an amplification oligonucleotide which in the presence of a target nucleic acid analyte and under amplification conditions is extended to form part of a nucleic acid extension product containing the target nucleic acid sequence or directs the synthesis of a nucleic acid transcription product containing the target nucleic acid sequence.

Tsang teaches a kit and the additional components of the claimed reaction mixture comprising a nucleic acid polymerase, nucleotide triphosphates and an amplification oligonucleotide which in the presence of a nucleic acid analyte and under amplification conditions is extended to form part of a nucleic acid extension product containing the target nucleic acid sequence or directs the synthesis of a nucleic acid transcription product containing the target nucleic acid sequence (see col. 2 lines 26-31).

With regard to claim 500, Tsang teaches one or more amplification oligonucleotides and the probe are present in the reaction mixture when the amplification reaction is initiated (see col. 8 Example 1, where the probe is included in the reaction mixture).

One of ordinary at the time the invention was made would have been motivated to incorporate the probe as taught by Carmo-Fonseca into a kit and a reaction mixture as taught by Tsang in order to detect the presence of a target nucleic acid. Tsang teach the use of the kit in a reaction mixture for amplification and detection of a target nucleic acid in a sample. It would have been prima facie obvious to incorporate

the probe of Carmo-Fonseca into a kit as taught by Tsang in order to detect a specific nucleic acid target using a kit which conveniently combines all of the elements needed for the reaction. Having all of the reagents necessary and available in one kit for detection saves time and money as you do not have to purchase the reagents individually. The kit also provides a means of quality control.

Response to Arguments

4. With respect to the previously made rejections, Applicants do not specifically point to the deficiencies of these rejections and therefore the rejections are maintained.

Summary

5. No claims were allowable.

Correspondence

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Heather Calamita
Art Unit 1637

12/18/2006